

THE BIOMEDICAL RESEARCH COMMUNITY: POWERING PROGRESS TOGETHER

Progress against cancer occurs when individuals in different segments of the biomedical research community work together. Further increasing collaboration between stakeholders will accelerate the pace of lifesaving progress in the future. The stakeholders in the biomedical research community include:

patients,
survivors, and
their caregivers,
family members,
and friends;



health care
providers;



academic and
government
researchers from
a diverse array
of specialties;



biotechnology,
pharmaceutical,
diagnostics, and
medical device
companies;



individual citizen
advocates and members
of advocacy groups;



policymakers;



regulators;



philanthropic organizations
and cancer-focused
foundations;



federal funding organizations; and



payers.



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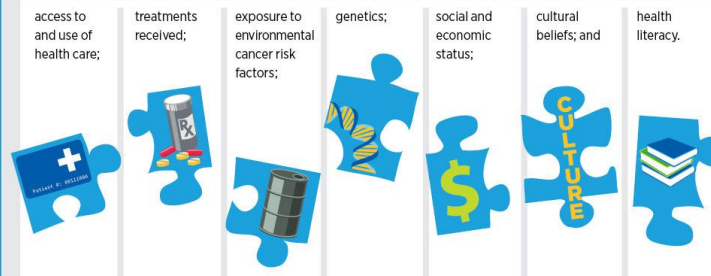
WHAT ARE CANCER HEALTH DISPARITIES?

According to the National Cancer Institute, cancer health disparities in the United States are defined as differences that should not exist in cancer incidence, prevalence, death, survivorship, and burden of cancer among certain segments of the U.S. population, including:



WHY DO THEY EXIST?

Complex and interrelated factors contribute to U.S. cancer health disparities. The factors may include, but are not limited to, differences or inequalities in:



The interrelated nature of many of these factors makes it difficult to isolate and study the relative contribution of each. Given that a significant proportion of the U.S. population falls into one or more risk categories, it is important that research into these specific issues continues. Only with new insights will we develop and implement interventions that will eliminate cancer for all.

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U.S. CANCER HEALTH DISPARITIES

Great strides have been made in cancer prevention, detection, diagnosis, treatment, and, in certain cases, cure. However, not all segments of the U.S. population have benefited equally from these advances. As a result, differences that should not exist in cancer incidence, prevalence, death, survivorship, and burden of cancer exist among certain segments of the U.S. population. Some examples of cancer health disparities are highlighted here:

27%
HIGHER

The overall cancer death rate among black men is 27 percent higher than among white men.

14%
HIGHER

The overall cancer death rate among black women is 14 percent higher than among white women.

**MORE THAN
DOUBLE**

Prostate cancer death rates among black men are more than double those for any other racial or ethnic group.

23%
MORE LIKELY

Hispanic children are 23 percent more likely to develop leukemia than non-Hispanic children.

2X

Asians and Pacific Islanders are about twice as likely to develop and die from liver cancer as their white counterparts.

62%
MORE LIKELY

American Indian/Alaska Native women are 62 percent more likely to develop kidney cancer than white women, and 80 percent more likely to die from the disease.

**R
I
S
K**

Colorectal cancer death rates in the lower Mississippi Delta, west central Appalachia, and eastern Virginia/North Carolina are elevated compared with the rest of the United States.

32%
LESS LIKELY

Advanced-stage ovarian cancer patients of low socioeconomic status are 32 percent less likely to receive standard overall care compared with those of high socioeconomic status.

**L
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Y**

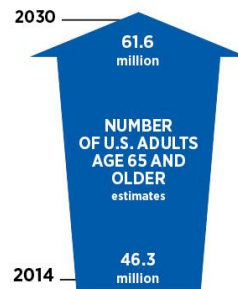
Lesbian women are less likely to undergo screening for breast and cervical cancer compared with heterosexual women; however, more research is needed to determine whether this finding translates into a disparity in cancer incidence.

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THE GROWING PUBLIC HEALTH CHALLENGE OF CANCER IN THE UNITED STATES



Cancer is a leading cause of morbidity and mortality in the United States. It is expected that the public health challenge it poses will grow considerably in the coming decades if more effective strategies for cancer prevention, early detection, and treatment are not developed.



This growing challenge will be fueled by an increase in the number of U.S. adults age 65 and older, continued use of cigarettes by 15 percent of U.S. adults, and high rates of obesity and physical inactivity.

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WHY DID I GET THIS CANCER?

Cancer initiation and progression are predominantly caused by the accumulation of changes, or mutations, in the genetic material of a cell over time. Some genetic mutations are inherited from your parents and are present in each cell of the body from birth but most genetic mutations are acquired during your lifetime.

Five to 10 percent of all new U.S. cancer cases are linked to inherited genetic mutations.



Some mutations are acquired during cell multiplication, and the number of times a cell multiplies increases the chance it will acquire a mutation.



Some mutations are acquired as a result of exposure to factors that damage genetic material, such as toxins in tobacco smoke and ultraviolet (UV) light from the sun.

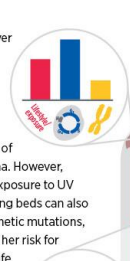


These factors come together to determine the chance that an individual cell has of acquiring mutations over time. This, in turn, helps determine the overall risk that a person will develop a particular type of cancer.

Simplified estimates of the relative contribution of each of the various sources of mutations to developing particular types of cancer are illustrated based on a recent study. This understanding can influence approaches for prevention and early detection of these and other types of cancer. Because cancer is caused by the accumulation of mutations over time, the older a person gets, the more likely he or she is to have a cell that has acquired a combination of genetic mutations causing it to become cancerous.

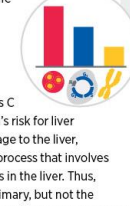
Basal Cell Carcinoma

Basal cells in the outermost layer of the skin are constantly multiplying to replace skin damaged by normal wear and tear. Thus, the number of cell multiplications is the primary contributor to the risk of developing basal cell carcinoma. However, it is not the only contributor. Exposure to UV radiation from the sun or tanning beds can also cause basal cells to acquire genetic mutations, and a person can reduce his or her risk for this cancer by adopting sun-safe habits and avoiding UV tanning devices.



Hepatitis C Virus-dependent Liver Cancer

Chronic infection with hepatitis C virus (HCV) increases a person's risk for liver cancer because it causes damage to the liver, which triggers a tissue-repair process that involves extensive multiplication of cells in the liver. Thus, chronic HCV infection is the primary, but not the only, contributor to the risk of developing liver cancer in infected individuals. HCV infection is treatable and preventable.



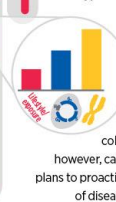
Smoking-dependent Lung Cancer

Acquired genetic mutations related to exposure to the toxins in cigarette smoke are the primary, but not the only, contributors to the risk of developing lung cancer. Eliminating tobacco use and exposure to smoke can prevent cancer from developing.



Familial Adenomatous Polyposis-dependent Colorectal Cancer

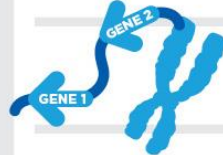
For individuals who inherit a mutation in the adenomatous polyposis coli (APC) gene, the inherited genetic mutation is the primary, but not the only, contributor to their risk of developing colorectal cancer. Such individuals, however, can alter their personal prevention plans to proactively survey for the earliest signs of disease and intervene as appropriate.



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GENETIC AND EPIGENETIC CONTROL OF CELL FUNCTION

Strings of four **deoxyribonucleic acid (DNA)** units called bases comprise the genetic material of a cell.



DNA bases are organized into **genes**. The order, or sequence, of the bases provides the code used by the cell to produce the various proteins it needs to function.



The entirety of a person's DNA is called the **genome**. Almost every cell in the body contains a copy of the genome. The genome is packaged together with proteins known as histones into structures called **chromosomes**.



Special chemical marks, called **epigenetic marks**, on the DNA and histones together determine whether a gene is accessible for reading. The sum of these chemical marks across the entire genome is called the **epigenome**.

The accessible genes within each cell are read to produce the proteins that ultimately define the **cell and tissue function** in which the cell resides.



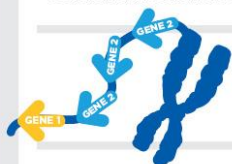
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GENETIC MUTATIONS

The following are some of the types of genetic mutation known to lead to cancer. Of note, genetic mutations do not always result in cancer.

Single base changes

- Some mutations can lead to the generation of altered versions of normal proteins, and these may cause cancer to develop.
- Deletion or insertion of a single base can result in new proteins or loss of protein function, which can lead to cancer.



Extra copies of genes (gene amplification)

Higher quantities of certain proteins can result in enhanced cell survival and growth, leading to cancer.

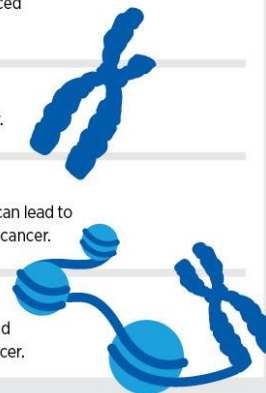
Large deletions

Loss of DNA can result in loss of genes necessary to stop or control the growth of cancer.



Genetic recombination

Exchange of DNA across different parts of the genome can lead to entirely new proteins that can drive the development of cancer.



Mutations that alter the epigenome

Several proteins read, write, or erase the epigenetic marks on DNA or the histones around which it is packaged. Mutations in the genes that produce these proteins can lead to cancer.

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CANCER GROWTH: LOCAL AND GLOBAL INFLUENCES

Solid tumors are much more complex than an isolated mass of proliferating cancer cells because cancer initiation, development, and progression are strongly influenced by interactions among cancer cells and numerous factors in their environment. Among the components of the tumor microenvironment are normal parts of the tissue in which the cancer is growing, systemic factors that transiently percolate through the tissue, and cells that are actively recruited to the tissue.

The **matrix** of proteins that surrounds the cancer cells can influence cancer formation, metastasis, and other processes.



Cancer cells can stimulate the growth of **blood and lymphatic vessel networks**, which supply the cancer cells with the nutrients and oxygen required for rapid growth and survival, and provide a route for cancer cell escape to distant sites (metastasis).

Systemic factors in the circulation, such as hormones and nutrients, influence the development and growth of cancer.



The **immune system** can identify and eliminate cancer cells, although in many cases this system is suppressed, permitting the formation and progression of a tumor. In some situations of chronic inflammation, however, the immune system can promote cancer development and progression.

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E-CIGARETTES: WHAT WE KNOW AND WHAT WE NEED TO KNOW

WHAT WE KNOW



While conventional cigarettes deliver nicotine by combusting tobacco, electronic cigarettes (e-cigarettes) deliver nicotine by vaporizing a nicotine solution.

460+ BRANDS

More than 460 brands of e-cigarettes and other electronic nicotine delivery systems (ENDS) are available.



More than 7,700 flavors of nicotine solutions are available.



E-cigarette use among U.S. middle and high school students is rapidly increasing.



In May 2016, the U.S. Food and Drug Administration announced it would begin regulating e-cigarettes, and banned the sale of these products to anyone under the age of 18.

WHAT WE NEED TO KNOW

ENDS and health

What are the health effects of acute and chronic ENDS use?



Does switching from cigarette smoking to ENDS use confer a health benefit?



Do different ENDS products vary in potential for addiction?



ENDS use

Who uses ENDS and why? Does this change over time?



Do flavorants affect the appeal and use of ENDS?



Does the marketing and availability of ENDS affect perception and use of ENDS?



Do tobacco-control policies affect the use of ENDS?



ENDS and cigarette smoking cessation



- Do ENDS aid cigarette smoking reduction and cessation?
- Can ENDS be used with current FDA-approved cessation medications?
- Should behavioral counseling be changed for ENDS cessation trials?
- Does short- or long-term ENDS use affect smoking relapse among those who have previously stopped using cigarettes?

ENDS products

- How do ENDS products differ from one other?
- Can ENDS product testing be standardized?



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ENHANCING TOBACCO CONTROL THROUGH FDA REGULATION

The U.S. Food and Drug Administration (FDA) has had the authority to regulate tobacco products since 2009. While the agency exercised regulatory authority over some of these products, such as cigarettes, others remained unregulated—until now. In 2016, the FDA extended its authority to cover all tobacco-based products through an amendment to the 2009 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). The key provisions of this extended rule include:

Permits FDA regulation of vaporizers, vape pens, cigars, hookah pens, e-cigarettes, e-pipes, and all other electronic nicotine delivery systems, as well as future tobacco products not yet on the market.



Requires a premarket review process and authorization of new tobacco products that reviews manufacturers' claims and requires the disclosure of ingredients and reporting of harmful or potentially harmful components.

Prohibits the sale of tobacco products to individuals under the age of 18 and requires the display of health warnings in advertisements and on tobacco and tobacco-related products.



Prohibits the distribution of free samples.



Defines content and size of warning labels and requires additional warnings for cigar packaging.

Defines establishments that mix or prepare e-liquids or create or modify aerosolizing apparatus for direct sale to consumers as tobacco product manufacturers that are subject to regulation as manufacturers.



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REDUCE YOUR RISK FOR CANCERS LINKED TO BEING OVERWEIGHT OR OBESE, BEING INACTIVE, AND/OR CONSUMING A POOR DIET

Research from the World Cancer Research Fund International shows that about one fifth of all U.S. cancers and one third of the most common types of cancer diagnosed in the United States are attributable to being overweight or obese, being inactive, and/or eating poorly. As such, among their recommendations are the following:

Be as lean as possible without becoming underweight, because 14 types of cancer have been causally linked to being obese or overweight.



Be physically active for at least 30 minutes every day, because regular physical activity can decrease risk for certain cancers.

Limit consumption of energy-dense foods (foods high in fats and/or added sugars and/or low in fiber) and avoid sugary drinks, because these contribute to weight gain.



Eat more of a variety of vegetables, fruits, whole grains, and beans, because these foods have a low energy density and, therefore, promote healthy weight.

Limit intake of red meat and avoid processed meat (e.g., hot dogs, bacon, and salami) because these foods can increase risk for colorectal cancer.



If consumed at all, limit alcoholic drinks, because alcohol consumption can increase risk for six types of cancer: breast, colorectal, esophageal, liver, stomach, and mouth/throat cancers.

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PHYSICAL ACTIVITY GUIDELINES

The U.S. Department of Health and Human Services recommends the following minimum physical activity levels to improve the nation's health; see <http://www.health.gov/paguidelines/guidelines/summary.aspx>.

FOR CHILDREN AND ADOLESCENTS

Sixty minutes or more of physical activity such as running daily.



Muscle- and bone-strengthening exercises such as pushups at least three days per week.



FOR ADULTS

All adults should avoid inactivity; some physical activity is better than none.



At least 150 minutes per week of moderate-intensity activity such as a brisk walk or 75 minutes per week of vigorous-intensity activity, such as running.



Moderate- or high-intensity muscle-strengthening activities two or more days per week.



FOR SPECIFIC POPULATIONS

Older adults, those who are pregnant, and/or those with disabilities should consult their physicians and the modified guidelines.



Cancer survivors should consult their physicians and follow modified guidelines adapted for their specific cancers and treatments.



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WAYS TO PROTECT YOUR SKIN

To reduce your risk of the three main types of skin cancer—basal cell carcinoma, squamous cell carcinoma, and melanoma—the Centers for Disease Control and Prevention recommend that you:

seek shade and limit time in the sun, especially around midday;



wear clothing that covers your arms and legs;

wear a wide-brimmed hat;



wear wrap-around sunglasses;

apply a sunscreen rated sun protection factor (SPF) 15 or higher at least every 2 hours and after swimming, sweating, and toweling off; and



avoid indoor tanning with UV devices like sunlamps, sunbeds, and tanning booths.

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INDOOR TANNING LEGISLATION

Use of an indoor UV tanning device increases a person's risk for melanoma by 20 percent, and each additional use increases risk a further 1.8 percent. The U.S. Food and Drug Administration is considering proposals that would ban the use of indoor UV tanning devices by people younger than age 18 and require manufacturers and indoor tanning facilities to take more actions to improve the overall safety of indoor UV tanning devices to protect adult consumers. As of July 31, 2016, legislation banning the use of indoor UV tanning devices by people younger than age 18 is already in place in numerous countries and several U.S. states:





- **Banned all indoor tanning—**
Brazil and Australia.
- **Banned indoor tanning for all people younger than 18—**
Austria, Belgium, Finland, France, Germany, Iceland, Italy, Norway, Portugal, Spain, and the United Kingdom, as well as California, Delaware, the District of Columbia, Hawaii, Illinois, Louisiana, Minnesota, Nevada, New Hampshire, North Carolina, Texas, and Vermont.
- **Banned indoor tanning for people younger than 18 unless they have a doctor's prescription—**
Oregon and Washington.



A number of other U.S. states have legislation that imposes less stringent restrictions on the use of indoor UV tanning devices, but eight states have no legislation restricting the use of such devices: Alaska, Colorado, Iowa, Kansas, Montana, New Mexico, Oklahoma, and South Dakota.

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PREVENTING OR ELIMINATING INFECTION WITH THE FOUR MAIN CANCER-CAUSING PATHOGENS

PATHOGEN	WAYS TO PREVENT INFECTION	WAYS TO ELIMINATE OR TREAT INFECTION	U.S. RECOMMENDATIONS
<i>Helicobacter pylori</i> 	None available	Treatment with a combination of antibiotics and a proton-pump inhibitor can eliminate infection.	CDC recommends testing and treatment for people with active or a documented history of gastric or duodenal ulcers, low-grade gastric MALT lymphoma, or early gastric cancer that has been surgically treated.
HBV 	<ul style="list-style-type: none"> • HBV vaccination. • Avoid behaviors that can transmit infection (e.g., injection drug use and unsafe sex). 	Treatment of those chronically infected with antiviral drugs rarely eliminates infection but does slow virus multiplication; this slows the pace at which liver damage occurs and thereby reduces risk for liver cancer.	<ul style="list-style-type: none"> • Vaccination part of childhood immunization schedule since 1991. • USPSTF recommends screening high-risk individuals—those from countries with high rates of HBV infection, HIV-positive persons, injection drug users, household contacts of HBV-infected individuals, and men who have sex with men—for HBV infection.
HCV 	Avoid behaviors that can transmit infection (e.g., injection drug use and unsafe sex).	Treatment with any of several antiviral drugs can eliminate infection.	CDC and USPSTF recommend screening those born from 1945 to 1965 for HCV infection.
HPV 	<ul style="list-style-type: none"> • Three FDA-approved vaccines. • Practice safe sex, although this may not fully protect against infection. 	None available.	<p>CDC recommends HPV vaccination for:</p> <ul style="list-style-type: none"> • boys and girls age 11 or 12. • women up to age 26 and men up to age 21 who did not receive the vaccine or complete the three-dose course as a preteen.

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HOW DO THE THREE FDA-APPROVED HPV VACCINES DIFFER?

13

strains of HPV can cause cancer:

HPV16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, and 66.

3

FDA-approved vaccines can prevent infection with some of these strains.



CERVARIX

- Protects against infection with HPV16 and HPV18.
- FDA approved in 2009.
- FDA approved for:
 - preventing cervical cancer and precancers.
 - vaccination of females ages 9 to 25.



GARDASIL

- Protects against infection with HPV16 and HPV18, as well as HPV6 and HPV11, which cause genital warts.
- FDA approved in 2006.
- FDA approved for:
 - preventing anal, cervical, vaginal, and vulvar cancers and precancers, as well as genital warts.
 - vaccination of males and females ages 9 to 26.



GARDASIL 9

- Protects against infection with HPV6, 11, 16, 18, 31, 33, 45, 52, and 58.
- FDA approved in 2014.
- FDA approved for:
 - preventing anal, cervical, vaginal, and vulvar cancers and precancers, as well as genital warts.
 - vaccination of females ages 9 to 26 and males ages 9 to 15.

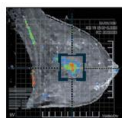
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Information is current as of July 2016

CANCERS FOR WHICH SCREENING TESTS EXIST

Highlighted here are cancer screening tests that have been used in the clinic to screen generally healthy individuals. When to use these tests and in whom is discussed elsewhere.

BREAST CANCER



Screening mammogram: Uses X-rays to image the breast.

The information generated by the procedure can be stored on film (a conventional mammogram) or electronically (a digital mammogram).

In most cases, the image is two-dimensional, but some machines generate three-dimensional images in a process called breast tomosynthesis.

Can detect breast cancers that cannot be felt. These cancers can be at any stage of development, but the aim of screening is to find them at the earliest possible stage.

CERVICAL CANCER



Pap test: Samples cervical cells, which are analyzed under a microscope to look for abnormalities.

Can detect precancerous or cancerous cervical lesions, but the aim of screening is to find them at the earliest possible stage.



HPV test: Detects the presence of certain cervical cancer-causing types of human papillomavirus (HPV).

Does not directly detect precancerous or cancerous cervical lesions, but identifies people for whom follow-up is recommended.

LUNG CANCER



Low-dose computed tomography (CT) scan: Uses low doses of X-rays to image the lungs.

Can detect lung cancers that are not causing symptoms. These cancers can be at any stage of development, but the aim of screening is to find them at the earliest possible stage.

PROSTATE CANCER



PSA test: Measures the level of the protein prostate-specific antigen (PSA) in blood.

Does not directly detect prostate cancer, but the blood level of PSA is often elevated in men with prostate cancer.

COLORECTAL CANCER



Stool tests: Some test for the presence of red blood cells in stool samples. Others test for both red blood cells and certain genetic mutations linked to colorectal cancer.

Do not directly detect colorectal precancerous lesions or cancers, but rather identify people for whom further testing is recommended.



Flexible sigmoidoscopy and colonoscopy:

Both use a thin, flexible, lighted tube with a small video camera on the end to allow physicians to look at the lining of certain parts of the colon and rectum.

Can detect colorectal precancerous lesions or cancers, but the aim of screening is to find them at the earliest possible stage so that they can be removed.



Computed tomography (CT) colonography (virtual colonoscopy) and double-contrast barium enema:

Use X-rays to image the colon and rectum.

Can detect colorectal precancerous lesions or cancers, but the aim of screening is to find them at the earliest possible stage so that they can be removed.



Blood test: Detects epigenetic abnormalities linked to colorectal cancer in blood (see [Increasing Options for Colorectal Cancer Screening](#), p. 57).

Does not directly detect colorectal precancerous lesions or cancers, but rather identifies people for whom further testing is recommended.

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CANCER SCREENING

BENEFITS OF SCREENING

Reduced cancer incidence. Screening tests can detect precancerous lesions. Removal of the lesions can reduce, or even eliminate, an individual's risk of developing the screened cancer at that spot.

Reduced incidence of advanced disease. Screening tests that detect developing cancers can reduce the individual's risk of being diagnosed with the screened cancer at a stage when it has spread to other parts of the body.

Reduced cancer mortality. Diagnosis at an early stage of disease can increase the likelihood that a patient can be successfully treated, which thereby reduces the individual's risk of dying from the screened cancer.



POTENTIAL RISKS OF SCREENING

Adverse events. Screening tests are medical procedures; thus, they carry some risk. However, the chance that an adverse event will occur during a screening test recommended by the U.S. Preventive Services Task Force (USPSTF) or a professional society is low.

Anxiety. Screening individuals who are not at high risk of disease can cause unnecessary anxiety during the waiting period for the test results.

False-positive test results. Not all individuals who have a positive screening test result have the screened cancer. The rates of false-positive test results vary depending on the test but are generally low; a false-positive screen can result in additional unnecessary medical procedures, treatments, and anxiety.

False-negative test results. Not all individuals who have a negative screening test result are free from the screened cancer. The rates of false-negative test results are generally low, but a false-negative screen can lead to missed opportunities for early treatment.

Overdiagnosis and overtreatment. Not all precancers or cancers detected by screening will go on to cause symptoms and threaten life. Overdiagnosis, as this is called, can lead to overtreatment, which may carry its own risks and costs. The rates of overdiagnosis and overtreatment vary among screening tests and are difficult to quantify.



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CONSENSUS AMONG CANCER SCREENING RECOMMENDATIONS

The U.S. Preventive Services Task Force (USPSTF) and many professional societies have evidence-based recommendations about the use of cancer screening tests. Here, we highlight consensus, as of July 31, 2016, among cancer screening recommendations from the USPSTF, the American Cancer Society (ACS), the National Comprehensive Cancer Network (NCCN), the American College of Physicians (ACP), the American College of Obstetrics and Gynecology (ACOG), and the American Urological Association (AUA). Not all of the professional societies have recommendations for every cancer screening test.



BREAST CANCER

There is consensus among the ACS, NCCN, and USPSTF that: women ages 50–74 who are at average risk for breast cancer should have regular screening mammograms. However, there is variability about whether this should be done every year or every other year.



CERVICAL CANCER

There is consensus among the ACOG, ACS, ACP, and USPSTF that:

- average-risk women younger than 21 should not be screened;
- average-risk women ages 21–29 should have a Pap test every 3 years;
- average-risk women ages 30–65 should have either a Pap test every 3 years or a Pap test and HPV testing every 5 years; and
- women older than 65 should not be screened if they have previously had regular screenings with normal results and are not otherwise at high risk for cervical cancer.



COLORECTAL CANCER

There is consensus among the ACS, ACP, NCCN, and USPSTF that:

- adults ages 50–75 who are at average risk for colorectal cancer should be screened; and
- adults ages 50–75 should consult with their health care providers to choose the test that is right for them.

Some professional societies, however, recommend certain approaches over others. The overall message is that using any one of the approved tests is better than not being screened.



LUNG CANCER

There is consensus among the ACS, ACP, and USPSTF that:

- screening with low-dose computed tomography should be limited to adults ages 55–79 who are at high risk for lung cancer because they have smoked at least one pack of cigarettes per day for 30 years, or the equivalent (two packs per day for 15 years, etc.), and who currently smoke or have quit within the past 15 years.

The USPSTF recommends annual screening for these individuals, whereas the ACS and ACP recommend these individuals talk to a physician about the benefits and potential harms of screening before deciding if it is right for them.



PROSTATE CANCER

There is little consensus among the ACS, ACP, AUA, NCCN, and USPSTF, with recommendations ranging from do not screen at all to screen regularly. That said, the ACS, ACP, and AUA all recommend that men ages 55–69 who are at average risk for prostate cancer talk to a physician about the benefits and potential harms of PSA testing before deciding if screening is right for them.

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HOW DO I KNOW IF I AM AT HIGH RISK FOR DEVELOPING AN INHERITED CANCER?

Among the factors to consider are whether, in your family, there is one or more of the following:

many cases of an uncommon or rare type of cancer (such as kidney cancer);

members diagnosed with cancers at younger ages than usual (such as colon cancer in a 20-year-old);

one or more members who have more than one type of cancer (such as a female relative with both breast and ovarian cancer); and

one or more members with cancers in both of a pair of organs (such as both eyes, both kidneys, or both breasts);

more than one childhood cancer in a set of siblings (such as sarcoma in both a brother and a sister);

members with a type of cancer usually occurring in the opposite sex (such as breast cancer in a man).

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DIRECT-TO-CONSUMER GENETIC TESTING

Direct-to-consumer (DTC) genetic tests are marketed directly to consumers, in contrast to tests that are ordered by a physician for a patient. This growing form of testing, also known as at-home testing, allows a consumer or patient to obtain access to his or her genetic information without necessarily involving a doctor or insurance company in the process. Below are a number of important facts about DTC genetic tests.

Potential Benefits of Using DTC Genetic Tests

These tests may encourage and empower consumers to take a proactive role in their health care.



Potential Risks of Using DTC Genetic Tests

These tests may mislead or misinform people about their health status.



DTC Genetic Tests and the FDA

DTC tests that claim to provide only information such as a person's ancestry or genealogy are not regulated by the U.S. Food and Drug Administration (FDA). In February 2015, however, the FDA authorized marketing of the first DTC genetic test: 23andMe's Bloom Syndrome carrier test. This test can help determine whether a healthy person has a variant in a gene that could lead to his or her children inheriting this serious disorder.



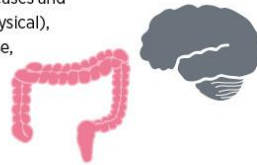
Because of the complexities of such tests, both the FDA and Federal Trade Commission recommend involving a health care professional in any decision to use DTC testing, as well as to interpret the results.

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BIOMEDICAL RESEARCH: WHAT IT IS AND WHO CONDUCTS IT

Biomedical research, as defined by the Organization for Economic Cooperation and Development (OECD), comprises:

The study of specific diseases and conditions (mental or physical), including detection, cause, prevention, treatment, and rehabilitation of persons.



The scientific investigation required to understand the underlying life processes that affect disease and human well-being, including areas such as the cellular and molecular bases of diseases, genetics, and immunology.



The design of methods, drugs, and devices used to diagnose, support, and maintain the individual during and after treatment for specific diseases or conditions.



Biomedical researchers are often categorized by the type of work they do, although some individuals perform several types of work and can be included in a number of categories. The types of biomedical researchers include, but are not limited to, the following:

Basic researchers study organisms, cells, molecules, or genes to gain new knowledge about cellular and molecular changes that occur naturally or during the development of a disease.



Clinical researchers conduct clinical trials; study a particular patient or group of patients, including their behaviors; or use materials from humans, such as blood or tissue samples, to learn about the way the healthy body works, disease, or response to treatment(s).



Population scientists, such as epidemiologists, social and behavioral scientists, and health services researchers, study the patterns, causes, costs, and effects of health and disease conditions in defined populations, or the effects of interventions on these conditions. These areas of research are highly collaborative and can span the spectrum from basic to clinical to population-wide research.



Physician-scientists care for patients and also conduct research. They may perform population, clinical, or basic research.



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RECLASSIFICATION OF BRAIN TUMORS

23,770
NEW CASES

16,050
DEATHS

Researchers estimate that 23,770 new cases of brain and other nervous system cancers will be diagnosed in the United States in 2016, and that there will be 16,050 deaths from these types of cancers.



There are many types of brain and central nervous system tumors. Most oncologists use the World Health Organization (WHO)

classification system to identify which of the many types of brain tumors a patient has. This information is vital to physicians and their patients as they understand the patient's outlook and decide which treatments are the best options.

In May 2016, the WHO updated the brain and central nervous system tumor classification system.



The previous classification system was based on identifying the cell type in which the tumor arose and how closely the cancer cells resemble the cell of origin.



The new classification system integrates molecular information about a patient's tumor with information on the cell of origin and how the cells look compared with the cell of origin. This reclassification was made possible by research that revealed the genetic and epigenetic variability among tumors previously thought to be of the same type.

The new classification system will allow physicians to more precisely diagnose and treat patients.

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THERAPEUTIC DEVELOPMENT



Target validation.

Potential therapeutic targets identified in discovery research are confirmed to play a causative role in a given disease.



Target to hit.

Large numbers of chemical or biological agents are screened to identify molecules that "hit" the target.



Hit to lead.

Positive hits are further tested to determine which bind the target with the most specificity.



Lead optimization.

The properties of the lead compound are refined to enhance potency and drug availability and to reduce side effects.



Preclinical testing.

Cellular and animal models are used to test for effectiveness of the optimized lead, identify any potential toxicity issues, and determine an optimal starting dose for clinical or "first-in-human" testing. The final compound is called the clinical candidate.

IND

Investigational new drug (IND).

Prior to clinical testing, one or more clinical candidates are submitted to the FDA for approval to be used in clinical trials.

5K-10K
COMPOUNDS

5-10 YEARS

1-5



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PHASES OF CLINICAL TRIALS

Clinical trials evaluating potential new anticancer therapeutics have traditionally been done in successive phases, each with an increasing number of patients.

PHASE I

Phase I studies are designed to determine the optimal dose of an investigational therapy and how humans process it, as well as to identify any potential toxicities. These first-in-human studies can also demonstrate early efficacy, or clinical results.

PHASE II

Phase II studies are designed to determine initial efficacy of an investigational therapy in a particular disease or selected group of patients, in addition to continually monitoring for adverse events or potential toxicities.

PHASE III

Phase III studies are large trials designed to determine therapeutic efficacy as compared to standard of care (placebos are rarely used in cancer clinical trials). When successful, the results of these trials can be used by regulators to approve new therapeutics or new indications for existing therapeutics.

PHASE IV

Phase IV studies are also known as post-marketing studies. They are conducted after a therapy is provisionally approved by the FDA and provide additional effectiveness or "real-world" data on the therapy.

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FDA'S EXPEDITED REVIEW STRATEGIES

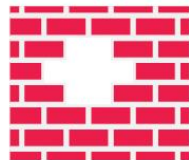
The U.S. Food and Drug Administration (FDA) has developed four evidence-based strategies to expedite assessment of therapeutics for life-threatening diseases like cancer.



Accelerated approval. Accelerated approval is based on assessing the effect of a therapeutic at an earlier stage by using a surrogate endpoint. Any therapeutic approved in this way must undergo additional testing following approval to verify that it provides clinical benefit. Atezolizumab (Tecentriq) for the treatment of advanced urothelial carcinoma (the most common form of bladder cancer) was approved under this pathway in May 2016.



Fast track. This designation is given to therapeutics that fill an unmet medical need and can be granted solely on the basis of preclinical data or data from nonhuman studies. Fast track applications may be evaluated through a "rolling" or continual review procedure, rather than waiting until study completion. Nivolumab (Opdivo) for the treatment of advanced renal cell carcinoma (the most common form of kidney cancer) was approved through fast track in November 2015.



Breakthrough therapy. A therapeutic that shows substantial improvement over available treatment in early clinical studies can receive breakthrough therapy designation, making it eligible for all features of fast track designation (see above) and additional guidance from the FDA throughout the drug development process. One example of a therapeutic that was FDA approved, in April 2016, after receiving a breakthrough therapy designation is venetoclax (Venclexta) for the treatment of chronic lymphocytic leukemia.



Priority review. Therapeutics that have the potential to significantly improve safety or effectiveness may be granted priority review after all clinical trials are completed. This allows the therapeutic to be assessed within 6 months as opposed to the standard 10 months. Alectinib (Alecensa) was granted priority review and approved in December 2015 for the treatment of certain patients with lung cancer.

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USING RADIATION IN CANCER CARE

There are two major uses of ionizing radiation in the diagnosis and treatment of cancer. Radiotherapy, or radiation therapy, uses high-energy radiation to control and eliminate cancer, whereas radiology largely uses lower-energy radiation to image tissues in order to diagnose disease or treat disease via the minimally invasive techniques used in interventional radiology.



RADIOTHERAPY



Radiotherapy is the use of high-energy rays (e.g., gamma rays and X-rays) or particles (e.g., electrons, protons, and carbon nuclei) to control or eliminate cancer.

It works chiefly by damaging DNA, leading to cell death.

TYPES OF RADIOTHERAPY

EXTERNAL BEAM RADIOTHERAPY directs radiation at the tumor from outside the body; it is the most common form of radiotherapy. Standard linear accelerators use electromagnetic fields to accelerate electrons, which can be used directly or collided with a metal target to generate high-energy X-rays. Electrons and photons (X-rays) are the most common sources of radiation in external beam radiotherapy.



PARTICLE THERAPY uses protons or carbon ions rather than X-rays as the source of energy. In contrast to X-rays that pass through the body, losing energy and causing damage to the noncancerous tissues through which they pass, these heavier particles deposit most of their energy in the target. In this manner, particle therapy can deliver higher doses with less damage to surrounding tissue. Although of great interest, proton facilities are much more expensive than traditional facilities, and the overall benefit to the patient is still being determined.

Conventional (2-D) external beam radiation therapy delivers a high-energy X-ray beam from one or multiple directions. Imaging of the treatment area is typically performed using low-energy diagnostic X-rays. It is chiefly used in settings where high precision is not required, such as in the treatment of bone metastases.



3-D conformational radiotherapy (3DCRT) uses specialized imaging, usually computed tomography (CT) and/or magnetic resonance imaging (MRI) and planning software, to deliver high-energy X-rays via multiple beams that more precisely fit the shape and size of the tumor.



Intensity-modulated radiotherapy (IMRT) is a further refinement of 3DCRT that more precisely focuses and shapes the radiation by dividing each beam into many "beamlets," each of which can have a different intensity. IMRT is particularly useful when a sharp dose gradient is required between the tumor and sensitive tissues, for example, the optic nerves.



Intraoperative radiation therapy uses electron beam (superficial) radiation directly on tumors that have been exposed during surgical procedures.



Stereotactic radiotherapy is used in both stereotactic surgery (SRS) and stereotactic body radiotherapy (SBRT). It uses many (typically more than eight) beams with a highly sophisticated imaging system to direct radiation to very well-defined smaller tumors. Typically, SRS is used to treat tumors of the brain and central nervous system, whereas SBRT can be used on small tumors within larger organs of the body.



USES OF RADIOTHERAPY



Radiotherapy is often used serially with surgery, chemotherapy, and/or immunotherapy to control or eliminate cancer.

CURATIVE radiotherapy seeks to completely eliminate a cancer, particularly small cancers, as well as locally advanced cancers as part of combination therapy.

NEOADJUVANT radiotherapy is used to reduce or control a cancer so that it can be subsequently treated by a different method such as surgery.

ADJUVANT radiotherapy seeks to eliminate any remaining cancer following prior treatment.

PALLIATIVE radiotherapy is used to reduce or control symptoms of disease when cure by another method is not possible.

TYPES OF RADIOTHERAPY

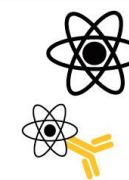


BRACHYTHERAPY places small radioactive sources in or next to the tumor. There are two forms of brachytherapy.

Permanent implantation inserts radioactive sources into the tumor; (e.g., placement directly into the prostate for the treatment of prostate cancer or into the tumor vasculature; see radioembolization below).



Temporary placement of radioactive sources. In one form of this treatment, moderately active sources are placed for 1 to 4 days (e.g., in the treatment of soft-tissue sarcoma). In "high dose-rate" brachytherapy, a highly active source is inserted for a few minutes (e.g., in the curative treatment of cervical cancer).



RADIOISOTOPE

Systemic ingestion or infusion of radioisotopes, which are natural or synthetic variations of elements that are unstable and emit high-energy rays as they stabilize, or radiolabeled therapeutics such as a therapeutic antibody. For example, the use of iodine-131 to treat thyroid cancer or yttrium-90 ibritumomab (Zevalin) to treat non-Hodgkin lymphoma, respectively.

INTERVENTIONAL RADIOLOGY

INTERVENTIONAL RADIOLOGY combines imaging with minimally invasive techniques designed to treat cancer locally.

Chemoembolization is a process by which therapeutic-coated particles are injected directly into the tumor vasculature in order to prevent blood flow and increase the therapeutic concentration to very high levels.



Cryoblation is a technique wherein needles are directly inserted into the tumor and cooled to very cold temperatures, causing tumor cell death.



High-intensity focused ultrasound applies high-intensity focused ultrasound waves to locally heat and destroy tumors.



Microwave ablation uses microwave radiation to locally heat and destroy tumors.



Radioembolization is the injection of radioactive microspheres directly into the tumor vasculature (e.g., injection of yttrium-90 microspheres into a liver tumor via the hepatic artery).



Radiofrequency ablation is a technique wherein needles are directly inserted into the tumor and an electrical current is used to heat the needle, causing tumor cell death.



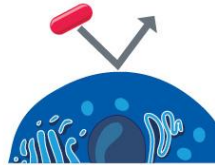
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THE CHALLENGE OF TREATMENT RESISTANCE

Diversity, or heterogeneity, among cancer cells within and between tumors is ultimately what leads to treatment resistance. Some examples of heterogeneity are as follows:



Some cancer cells in a tumor may contain mutations in the target of a given treatment that render the treatment ineffective.



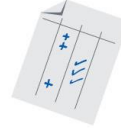
Redundancies among signalling networks fueling proliferation can enable cancer cells to become resistant to a treatment.

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COMPANION DIAGNOSTICS

The effective therapeutic use of precision medicines targeting particular cancer-driving molecular abnormalities often requires tests called companion diagnostics. Companion diagnostics:

are stringently tested for accuracy, sensitivity, and fidelity;



are regulated by the U.S. Food and Drug Administration;

accurately match patients with the most appropriate therapy;



allow patients to receive a treatment to which they are most likely to respond; and

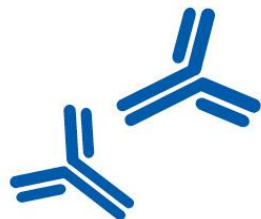
allow patients identified as very unlikely to respond to forgo treatment with the therapeutic and thus be spared any adverse side effects.



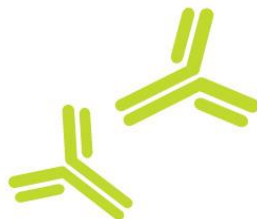
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RECENT ADVANCES AGAINST MULTIPLE MYELOMA

Daratumumab (Darzalex) is an immunotherapeutic that was approved by the FDA in November 2015 for treating multiple myeloma that has progressed despite treatment with at least three prior therapies, including a proteasome inhibitor and an immunomodulatory agent.



Elotuzumab (Empliciti) is an immunotherapeutic that was approved by the FDA in November 2015 for use in combination with lenalidomide (Revlimid) and dexamethasone for multiple myeloma that has progressed despite treatment with one to three prior treatments.



Ixazomib (Ninlaro) is a proteasome inhibitor that was approved by the FDA in November 2015 for use in combination with lenalidomide and dexamethasone for treating multiple myeloma that has progressed despite treatment with at least one prior treatment.



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HOW IMMUNOTHERAPEUTICS WORK

The way in which different immunotherapeutics work to benefit patients varies:

Some release the brakes on the natural cancer-fighting power of the immune system, for example, atezolizumab (Tecentriq).



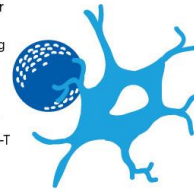
Some increase the killing power of the immune system by providing more cancer-targeted immune cells called T cells; these are called adoptive T-cell therapies, for example CTL019 and JCAR015 [for more information on these immunotherapeutics see the *AACR Cancer Progress Report 2015*].



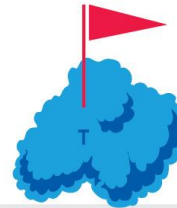
Some boost the killing power of the immune system by enhancing T-cell function, for example, interleukin-2 (Aldesleukin).



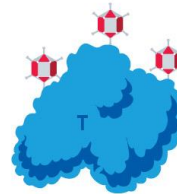
Some enhance the cancer-killing power of the immune system by triggering cancer-fighting T cells; these are called therapeutic cancer vaccines, for example, sipuleucel-T (Provenge).



Some flag cancer cells for destruction by the immune system, for example, daratumumab (Darzalex) and elotuzumab (Empliciti).



Some comprise a virus that preferentially infects and kills cancer cells, releasing molecules that trigger cancer-fighting T cells; these are called oncolytic virotherapeutics, for example, talimogene laherparepvec (T-Vec; Imlygic).



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KEY PLAYERS IN THE IMMUNE SYSTEM

White blood cells are the cells of the immune system that work together to protect the body from pathogens. They can also cooperate to attack and destroy cancer cells. Here, we describe briefly the unique functions of the white blood cells that have a central role in these processes.



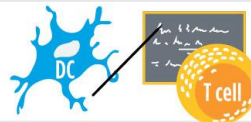
B cells make antibodies that help the immune system function. Some remain as memory B cells to make the same antibody again later, if it is needed.

CD4+ T cells help manage the immune response. Some remain as memory T cells to fight again later.



CD8+ T cells kill infected, damaged, and cancer cells. Some remain as memory T cells to fight again later.

Dendritic cells educate T cells about what kinds of cells they should and should not attack.



Macrophages eat foreign materials.

Mast cells release chemicals against pathogens and stimulate the immune system.



Natural killer (NK) cells kill infected, damaged, and cancer cells.

Neutrophils, basophils, and eosinophils release chemicals against pathogens and stimulate the immune system.



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LIFE AFTER A CANCER DIAGNOSIS IN THE UNITED STATES

When an individual becomes a cancer survivor, his or her life is changed irrevocably. Cancer survivors often face serious and persistent adverse outcomes, including physical, emotional, psychosocial, and financial challenges, as a result of the cancer diagnosis and treatment.

Among the challenges experienced from the time from diagnosis to the end of initial treatment are:



choosing a physician(s)
and treatment facility;



choosing among a variety of
treatment options; and



managing side effects of cancer
and cancer treatment, many
of which persist long term.

Many challenges experienced by cancer survivors begin during cancer treatment and continue long term, but others can appear months or even years later. These long-term and late effects include, but are not limited to:



bone density loss (osteoporosis);



cognitive impairment, sometimes
known as "chemo brain";



diagnosis with a new
form of cancer(s);

DISTRESS

distress, which can interfere with
a person's ability to cope effectively
with cancer and its treatment;

FATIGUE

fatigue that is severe and often
not relieved by rest;

FEAR

fear of cancer recurrence;



heart damage (cardiotoxicity);

INFERTILITY

infertility;



lung (pulmonary) damage;



lymphedema: swelling, most
often in the arms or legs, that
can cause pain and problems in
functioning;



pain;



premature
aging;



recurrence of
original cancer; and

SEXUAL DYSFUNCTION

sexual dysfunction.

Although all cancer survivors face challenges, some segments of the population experience more than others.

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SURVIVING A CANCER DIAGNOSIS AS A CHILD OR ADOLESCENT

380,000

Almost 380,000 survivors of cancer diagnosed by

the age of 19, when they were a child or adolescent, were alive on Jan. 1, 2010. Individuals in this group face long-term physical and emotional health challenges. For example:

98%

98 percent of adult survivors of childhood cancer have one or more chronic

health conditions and 68 percent have severe/disabling or life-threatening conditions.

5%

5 percent of survivors of a cancer diagnosed in childhood

develop a second cancer between 5 and 30 years after their initial diagnosis.

The Children's Oncology Group "Long-Term Follow-Up Guidelines for Survivors of Childhood, Adolescent, and Young Adult Cancers" were developed to help standardize and enhance the lifelong follow-up care of individuals who were diagnosed with cancer as a child, adolescent, or young adult. For more information, see <http://survivorshipguidelines.org/>.

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WHAT IS PALLIATIVE CARE?

It is specialized care that provides an extra layer of support to patients with serious illnesses such as cancer and their families.

It is not the same as hospice care, because it can be given throughout a patient's experience with cancer, beginning at diagnosis and continuing through treatment, follow-up, survivorship, and end-of-life care.

It can be given in addition to cancer treatment or to those with no curative treatment options; palliative care given near the end of life is usually referred to as hospice care.

Palliative care addresses many of the challenges that can affect quality of life after a cancer diagnosis, including:

- emotional challenges such as anxiety and depression;
- physical symptoms and adverse effects of the disease and its treatment, such as pain, nausea, vomiting, fatigue, difficulty sleeping, and loss of appetite;
- practical challenges such as navigating the health care system; and
- spiritual challenges.

WHO PROVIDES PALLIATIVE CARE?

Any health care provider can provide primary palliative care by addressing the adverse effects and emotional issues facing a patient with cancer, but some specialize in this area of patient care.

Palliative care specialists usually work as part of multidisciplinary team that includes doctors, nurses, registered dietitians, pharmacists, social workers, psychologists, and chaplains.

The palliative care team works alongside the physicians treating the patient's cancer.

WHO CAN RECEIVE PALLIATIVE CARE?

Any patient diagnosed with a serious illness, such as cancer, including children.

The family members and friends of a patient diagnosed with a serious illness can receive palliative care to help provide them the support they need.

WHERE CAN PATIENTS RECEIVE PALLIATIVE CARE?

Palliative care is most widely available in hospital settings, but a team can also provide it at home, over the phone, or in an outpatient clinic.

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CRISPR 101

Investigating the effects of changing, or editing, the genetic material of a cell is an important part of biomedical research. It is particularly vital during the discovery phase of biomedical research and in therapeutic development.



CRISPR is a revolutionary approach to gene editing that has emerged in the past 2 or 3 years (197).

It provides a faster and more precise and efficient approach to gene editing compared with previous technologies.



The development of CRISPR technology was based on research into the immune system of certain species of bacteria.

CRISPR technology is being used by researchers throughout the biomedical research community in numerous ways and is being investigated as a potential way to treat certain genetic diseases and to modify certain approaches to immunotherapy.



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BUILDING BLOCKS OF FURTHER PROGRESS AGAINST CANCER

To accelerate the pace of progress against cancer, we must:

Prioritize and increase federal funding for biomedical research.



Support cross-cutting initiatives to advance progress against cancer.



Support regulatory science initiatives.



Develop and train the biomedical research workforce of tomorrow.



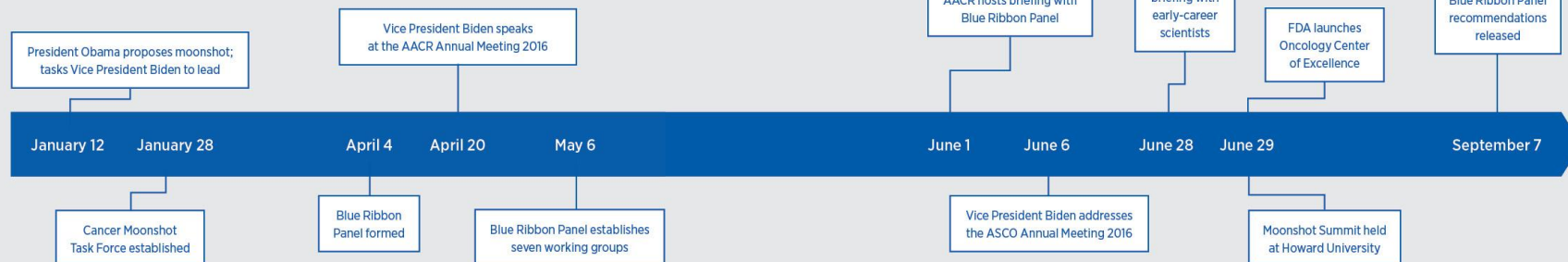
Support precision prevention efforts.



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THE NATIONAL CANCER MOONSHOT INITIATIVE

The National Cancer Moonshot Initiative seeks to double the rate of progress toward a cure for cancer by achieving 10 years of progress in 5 years. The initiative is led by Vice President Joe Biden and a federal interagency task force. A Blue Ribbon Panel, and its seven working groups, provide scientific advice to the Task Force.



BLUE RIBBON PANEL

- Tyler Jacks, PhD (Co-Chair)
- Elizabeth M. Jaffee, MD (Co-Chair)
- Dinah S. Singer, PhD (Co-Chair)
- Peter C. Adamson, MD
- James P. Allison, PhD
- David F. Arons, JD
- Mary C. Beckerle, PhD
- Mitchel S. Berger, MD
- Jeffrey A. Bluestone, PhD
- Chi Van Dang, MD, PhD
- Mikael Dolsten, MD, PhD
- James R. Downing, MD

- Levi A. Garraway, MD, PhD
- Gad Getz, PhD
- Laurie H. Glimcher, MD
- Lifang Hou, MD, PhD
- Neal Kassell, MD
- Maria Elena Martinez, PhD
- Deborah Mayer, PhD, RN
- Edith P. Mitchell, MD, FAC
- Augusto C. Ochoa, MD
- Jennifer A. Pietenpol, PhD
- Angel Pizarro, MSE
- Barbara K. Rimer, DrPH
- Charles L. Sawyers, MD
- Ellen V. Sigal, PhD
- Patrick Soon-Shiong, MD, FRCS (C), FACS
- Wai-Kwan Alfred Yung, MD

EX OFFICIO MEMBERS OF THE BLUE RIBBON PANEL ARE:

- David Atkins, MD, MPH
- Robert M. Califf, MD
- Karen S. Gulce, MD, MPP
- Jason Paragas, PhD
- Lawrence A. Tabak, DDS, PhD

7

working groups developed recommendations and evaluated others from the community and the public.

BLUE RIBBON PANEL RECOMMENDATIONS

- 1. Network for direct patient engagement**
Encourages patients to have their tumor genome sequenced, automatically shares the results through a network of linked databases, and enables clinical trial enrollment when appropriate.
- 2. Cancer immunotherapy clinical trials network**
A network of clinical trials in adult and pediatric patients to evaluate immunotherapies and vaccines.
- 3. Therapeutic target identification to overcome drug resistance**
Methods to identify mechanisms of drug resistance and develop therapeutic strategies to prevent and overcome it.
- 4. A national cancer data ecosystem for sharing and analysis**
Develops the computational and bioinformatic infrastructure necessary to share any kind of data with anyone while maintaining privacy and security.
- 5. Fusion oncoproteins in pediatric cancer**
Develop new therapeutics targeting pediatric fusion proteins through the use of new research models.
- 6. Symptom management research**
Use patient reported outcomes to develop evidence-based guidelines to manage patient symptoms throughout the course of clinical care.
- 7. Prevention and early detection: Implementation of evidence-based approaches**
Use research to discover, test, and implement strategies to reduce cancer risk, with an initial focus on fully executing established risk-reduction strategies.
- 8. Retrospective analysis of biospecimens from patients treated with standard of care**
Analyze existing and future samples from patients receiving standard of care to enable the precise use of standard treatments and catalyze additional research.
- 9. Generation of human tumor atlases**
Develop comprehensive maps of all of the alterations within as many different tumors as possible to fully enable precision medicine.
- 10. Development of new enabling cancer technologies**
The new technologies will be used to enable further discoveries and improve patient care.

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AACR American Association
for Cancer Research
FINDING CURES TOGETHERSM

FDA ONCOLOGY CENTER OF EXCELLENCE



On June 29, 2016, U.S. Food and Drug Administration (FDA) Commissioner Robert Califf announced the creation of a new Oncology Center of Excellence (OCE) at the FDA, and he appointed Richard Pazdur, MD, as acting director. This new center, which will play a key role in advancing the National Cancer Moonshot Initiative, will leverage the combined skills of regulatory scientists and reviewers with expertise in drugs, biologics, and devices to expedite the development of novel combination products for the benefit of patients with cancer. The new FDA OCE will bring staff from all the important areas of the cancer drug development process together to fuel the progress we are seeing today in preventing, detecting, and treating cancer.

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